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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,900	11/20/2003	Xue Mei Zhou	3528.1	3341

22886 7590 03/31/2006

AFFYMETRIX, INC
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.
3420 CENTRAL EXPRESSWAY
SANTA CLARA, CA 95051

EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,900

Applicant(s)

ZHOU, XUE MEI

Examiner

Jehanne S. Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 7-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/06, 7/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 7-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 11/28/2005.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to an array comprising a plurality of nucleic acid probes wherein the array comprises each of the sequences listed in SEQ ID NOS 1-982,914. The claims are further drawn to an array comprising the complements of each SEQ ID NO., as well as probes in which one of the sequences listed in SEQ ID NOS 1-982,914 has a mismatch at the central position.

The specification teaches that the sequences of SEQ ID NOS 1-982,914 correspond to regions of the mouse genome for at least 30,000 mouse genes (page 22). The specification teaches that for each of SEQ ID NO: 1-982,914 the “disclosure” includes probes with a mismatch anywhere in the nucleic acid sequence and may comprise one or more bases (page 18, lines 6-10).

The specification asserts that the array can be used to measure gene expression (page 18), such as to determine the effects of a drug on gene expression (page 22), to be used as probes for their complementary genes listing in genbank (page 21), to identify biallelic markers (page 24), use for cross-species comparisons (page 25), to characterize the genotype of knockouts (page 26), to identify new gene family members (page 26), and to provide nucleic acids to be used as tag sequences (page 26).

The claimed nucleic acids/array are not supported by a specific asserted utility because the disclosed uses of the nucleic acids on the array are not specific and are generally applicable to any nucleic acid. These are non-specific uses that are applicable to any nucleic acids containing SNPs are not particular or specific to the nucleic acids and array being claimed.

Further, the claimed nucleic acids/array are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. While the nucleic acids may be utilized as asserted, the specification provides no association with any useful effect of drugs related to gene expression, no biallelic markers with any known phenotype (ie pharmacogenomic association for drug metabolism), disorder, disease, relevance of expression of any particular gene, etc so that one of skill in the art would be able to use the claimed array in a real world context of use. The array can be used to search for a utility, but significant

unpredictable experimentation must be undertaken to establish an association between the probes and any particular phenotype such as drug effects, disease, etc. The need for such research clearly indicates that the products are not disclosed as to a currently available or substantial utility. The research contemplated by applicant(s) to characterize the products, does not constitute a specific and substantial utility. Identifying and studying the properties of a compound itself or the mechanisms in which it is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid such that another non-asserted utility would be well established for the compounds.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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7. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an array comprising a plurality of nucleic acid probes wherein the array comprises each of the sequences listed in SEQ ID NOS 1-982,914. The claims are further drawn to an array comprising the complements of each SEQ ID NO:, as well as probes in which one of the sequences listed in SEQ ID NOS 1-982,914 has a mismatch at the central position.

The specification teaches that the sequences of SEQ ID NOS 1-982,914 correspond to regions of the mouse genome for at least 30,000 mouse genes (page 22). The specification teaches that for each of SEQ ID NO: 1-982,914 the “disclosure” includes probes with a mismatch anywhere in the nucleic acid sequence and may comprise one or more bases (page 18, lines 6-10). It appears that the specification contemplates mutations at any position along the disclosed SEQ ID NOS which have not been taught by the specification. Additionally, the claims recite probes “comprising” one of the sequences of SEQ ID NOS 1-982,914, which encompass an extremely large genus of full length genes, cDNAs, and variants, which need only minimally comprise the recited 25 mers, which have not been taught by the specification. The specification at page 32, states that the pool of unique sequences are complementary to approximately 36,000 full length mouse genes and EST clusters from Unigene database build 107. Such disclosure,

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however, does not provide for any fixed sequences comprising the claimed SEQ ID NOS as the information in database can be changed.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of an array comprising nucleic acid probes each probe consisting of one of SEQ ID NOS: 1-982,914 the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it

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obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Affymetrix Murine Genome U74 Set, version 2 (March, 2001).

The murine Genome U74 set is disclosed as a set of arrays of nucleic acid probes from the murine genome including greater than 36,000 mouse genes and ESTs. The instant specification teaches that SEQ ID NOS 1-982,914 are probes to greater than 36,000 mouse genes and ESTs. Although the product sheet does not specifically teach the sequences of SEQ ID NOS 1-982,914, such is considered an inherent property of the U74 array. As stated in the MPEP in chapter 2100:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In *re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In *re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the instant case, the teaching is applicant's own work, the PTO has basis for believing that the array set contains the sequences of SEQ ID NOS 1-982,914.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Affymetrix Murine Genome U74 Set, version 2 (March, 2001) in view of Fodor et al (US Patent 6,309,822; 10/2001).

The murine Genome U74 set is disclosed as a set of arrays of nucleic acid probes from the murine genome including greater than 36,000 mouse genes and ESTs. The instant specification teaches that SEQ ID NOS 1-982,914 are probes to greater than 36,000 mouse genes and ESTs. Although the product sheet does not specifically teach the sequences of SEQ ID NOS

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1-982,914, such is considered an inherent property of the U74 array. As stated in the MPEP in chapter 2100:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the instant case, the teaching is applicant's own work, the PTO has basis for believing that the array set contains the sequences of SEQ ID NOS 1-982,914. Murine Genome U74 Set is taught to include probes on different arrays, and not on a single contiguous solid support. However, Fodor teaches that there is a need to provide microfabricated arrays of large numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1 cm². Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to provide the probes of Affymetrix murine genome U74 Set on a single contiguous solid support because Fodor teaches that there is a need to provide microfabricated arrays of large numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1 cm². The ordinary artisan would have been motivated to modify the arrays of Affymetrix murine genome U74 set to also provide the probes on a single contiguous solid support for the purpose of providing a single support, and therefore provide versatility for those practitioners requiring all probes in the U74 set, with the probe information for the murine genome for use in expression profile analysis.

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13. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unigene build 107 (June 2002) in view of Fodor et al (US Patent 6,309,822; 10/2001).

The claims are drawn to arrays comprising probes which comprise one of SEQ ID NOS 1-982,914, wherein the probes of the array comprises each of SEQ ID NOS 1-982,914. Accordingly, the array comprises at least 982,914 probes, each probe comprising one of SEQ ID NOS 1-982,914. Claim 2 is further drawn to the array comprising at least one probe which is the complement of one of the sequences of claim 1. Claim 3 is further drawn to the array comprising at least one mismatch probe corresponding to one of the sequences of claim 1. Claim 4 is drawn to a solid support with the probes attached thereto. Claim 5 is further drawn to the array which comprises a plurality of beads, wherein the probes are attached to the beads and the probes on a bead consist essentially of one of the sequences listed in claim 1. Claim 6 is drawn to the support as a single contiguous solid support.

Unigene build 107 teaches the sequences of mouse genes and ESTs. Absent evidence to the contrary, the build listed above, is taken to provide the sequence information of SEQ ID NOS 1-982,914. The Unigene database does not teach probes comprising each of SEQ ID NOS 1-982,914, however Fodor teaches that there is a need to provide microfabricated arrays of large numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1 cm², wherein sets of probes are chosen to be complementary over a gene sequence (col. 14). With regard to claims 2-3, Fodor teaches that the probes are preferably 20 or 25 nucleotides in length, and include normalization controls drawn to the complement of a probe designed from a particular target DNA sequence, as well as mismatch controls and normalization control probes

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(col. 22, lines 45-65). With regard to claims 4-5, Fodor teaches that the oligonucleotides in the array can be provided attached to beads (col. 21), including individual probes attached to each bead. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have constructed an array of probe sets of 25 nucleotides, for genes and ESTs in the unigene database for the purpose of providing an array of probes for gene expression analysis as taught by Fodor. The ordinary artisan would have been motivated to provide an array of probe sets for murine sequences because Fodor teaches to provide arrays for gene expression monitoring.

14. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unigene build 74 in view of Fodor et al (US Patent 6,309,822; 10/2001).

The claims are drawn to arrays comprising probes which comprise one of SEQ ID NOS 1-982,914, wherein the probes of the array comprises each of SEQ ID NOS 1-982,914. Accordingly, the array comprises at least 982,914 probes, each probe comprising one of SEQ ID NOS 1-982,914. Claim 2 is further drawn to the array comprising at least one probe which is the complement of one of the sequences of claim 1. Claim 3 is further drawn to the array comprising at least one mismatch probe corresponding to one of the sequences of claim 1. Claim 4 is drawn to a solid support with the probes attached thereto. Claim 5 is further drawn to the array which comprises a plurality of beads, wherein the probes are attached to the beads and the probes on a bead consist essentially of one of the sequences listed in claim 1. Claim 6 is drawn to the support as a single contiguous solid support.

Unigene build 74 teaches the sequences of mouse genes and ESTs. Absent evidence to the contrary, the build listed above, is taken to provide the sequence information of SEQ ID NOS 1-982,914. The Unigene database does not teach probes comprising each of SEQ ID NOS 1-982,914, however Fodor teaches that there is a need to provide microfabricated arrays of large numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1 cm², wherein sets of probes are chosen to be complementary over a gene sequence (col. 14). With regard to claims 2-3, Fodor teaches that the probes are preferably 20 or 25 nucleotides in length, and include normalization controls drawn to the complement of a probe designed from a particular target DNA sequence, as well as mismatch controls and normalization control probes (col. 22, lines 45-65). With regard to claims 4-5, Fodor teaches that the oligonucleotides in the array can be provided attached to beads (col. 21), including individual probes attached to each bead. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have constructed an array of probe sets of 25 nucleotides, for genes and ESTs in the unigene database for the purpose of providing an array of probes for gene expression analysis as taught by Fodor. The ordinary artisan would have been motivated to provide an array of probe sets for murine sequences because Fodor teaches to provide arrays for gene expression monitoring.

15. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall, (Science, vol. 296, May 10, 2002; page 1005) in view of Fodor et al (US Patent 6,309,822; 10/2001).

The claims are drawn to arrays comprising probes which comprise one of SEQ ID NOS 1-982,914, wherein the probes of the array comprises each of SEQ ID NOS 1-982,914. Accordingly, the array comprises at least 982,914 probes, each probe comprising one of SEQ ID NOS 1-982,914. Claim 2 is further drawn to the array comprising at least one probe which is the complement of one of the sequences of claim 1. Claim 3 is further drawn to the array comprising at least one mismatch probe corresponding to one of the sequences of claim 1. Claim 4 is drawn to a solid support with the probes attached thereto. Claim 5 is further drawn to the array which comprises a plurality of beads, wherein the probes are attached to the beads and the probes on a bead consist essentially of one of the sequences listed in claim 1. Claim 6 is drawn to the support as a single contiguous solid support.

Marshall teaches the completion of the draft of the sequence of the mouse genome. As the sequence information is taught to consist of 96% of the mouse genome, the PTO has basis for believing that it contains the sequence information of SEQ ID NOS 1-982,914. As stated in the MPEP in chapter 2100:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Marshall does not teach probes comprising each of SEQ ID NOS 1-982,914, however Fodor teaches that there is a need to provide microfabricated arrays of large numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1

cm², wherein sets of probes are chosen to be complementary over a gene sequence (col. 14).

With regard to claims 2-3, Fodor teaches that the probes are preferably 20 or 25 nucleotides in length, and include normalization controls drawn to the complement of a probe designed from a particular target DNA sequence, as well as mismatch controls and normalization control probes (col. 22, lines 45-65). With regard to claims 4-5, Fodor teaches that the oligonucleotides in the array can be provided attached to beads (col. 21), including individual probes attached to each bead. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have constructed an array of probe sets of 25 nucleotides, for sequences in the mouse genome, as taught by Marshall, for the purpose of providing an array of probes for gene expression analysis as taught by Fodor. The ordinary artisan would have been motivated to provide an array of probe sets for murine sequences database because Fodor teaches to provide arrays for gene expression monitoring.

16. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall II, (Marshall, Science, vol. 292, May 4, 2001; page 822) in view of Fodor et al (US Patent 6,309,822; 10/2001).

The claims are drawn to arrays comprising probes which comprise one of SEQ ID NOS 1-982,914, wherein the probes of the array comprises each of SEQ ID NOS 1-982,914. Accordingly, the array comprises at least 982,914 probes, each probe comprising one of SEQ ID NOS 1-982,914. Claim 2 is further drawn to the array comprising at least one probe which is the complement of one of the sequences of claim 1. Claim 3 is further drawn to the array comprising at least one mismatch probe corresponding to one of the sequences of claim 1.

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Claim 4 is drawn to a solid support with the probes attached thereto. Claim 5 is further drawn to the array which comprises a plurality of beads, wherein the probes are attached to the beads and the probes on a bead consist essentially of one of the sequences listed in claim 1. Claim 6 is drawn to the support as a single contiguous solid support.

Marshall II teaches the completion of the draft of the sequence of the mouse genome. As the sequence information is taught to consist of the mouse genome, the PTO has basis for believing that it contains the sequence information of SEQ ID NOS 1-982,914. As stated in the MPEP in chapter 2100:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Marshall II does not teach probes comprising each of SEQ ID NOS 1-982,914, however Fodor teaches that there is a need to provide microfabricated arrays of large numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1 cm², wherein sets of probes are chosen to be complementary over a gene sequence (col. 14). With regard to claims 2-3, Fodor teaches that the probes are preferably 20 or 25 nucleotides in length, and include normalization controls drawn to the complement of a probe designed from a particular target DNA sequence, as well as mismatch controls and normalization control probes (col. 22, lines 45-65). With regard to claims 4-5, Fodor teaches that the oligonucleotides in the array can be provided attached to beads (col. 21), including individual probes attached to each

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bead. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have constructed an array of probe sets of 25 nucleotides, for sequences in the mouse genome, as taught by Marshall II, for the purpose of providing an array of probes for gene expression analysis as taught by Fodor. The ordinary artisan would have been motivated to provide an array of probe sets for murine sequences database because Fodor teaches to provide arrays for gene expression monitoring.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jehanne Sitton

Primary Examiner

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3/6/06